SIMULATIONS PLUS INC Form 10-K November 29, 2011

Act.

Yes [\_] No [X]

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

#### FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended August 31, 2011
or
[_]TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 001-32046
Simulations Plus, Inc.
(Exact name of registrant as specified in its charter)
California 95-4595609
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)
42505 Tenth Street West
Lancaster, CA 93534-7059 (661) 723-7723
(Address of principal executive offices including (Registrant's telephone number, including zip code) area code)
SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:
Title of Each Class Name of Each Exchange on Which
Common Stock, par value \$0.001 per share Registered NASDAQ Stock Market LLC
SECURITIES REGISTERED UNDER SECTION 12(G) OF THE ACT: NONE
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [_] No [X]
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filings requirements for the past 90 days.  Yes [X] No [_]
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes [_] No [_]
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [_]
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):  [_] Large accelerated filer  [_] Non-accelerated filer (Do not check if a smaller reporting  [X] Smaller reporting company company
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [_] No [X]
The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of February 28, 2011, based upon the closing price of the common stock as reported by The Nasdaq Stock Market on such date, was approximately \$28,608,254. This calculation does not reflect a determination that persons are affiliates for any other purposes.
As of November 28, 2011, 15,572,943 shares of the registrant's common stock, par value \$0.001 per share were outstanding, and no shares of preferred stock were outstanding.
DOCUMENTS INCORPORATED BY REFERENCE
Certain portions of the definitive Proxy Statement to be delivered to shareholders in connection with the 2012 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K.

## Simulations Plus, Inc. FORM 10-K For the Fiscal Year Ended August 31, 2011

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#### Forward-Looking Statements

This document and the documents incorporated in this document by reference contain forward-looking statements that are subject to risks and uncertainties. All statements other than statements of historical fact contained in this document and the materials accompanying this document are forward-looking statements.

The forward-looking statements are based on the beliefs of our management, as well as assumptions made by and information currently available to our management. Frequently, but not always, forward-looking statements are identified by the use of the future tense and by words such as "believes," expects," "anticipates," "intends," "will," "may," "c "would," "projects," "continues," "estimates" or similar expressions. Forward-looking statements are not guarantees of future performance and actual results could differ materially from those indicated by the forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements.

The forward-looking statements contained or incorporated by reference in this document are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended ("Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. These statements include declarations regarding our plans, intentions, beliefs or current expectations.

Among the important factors that could cause actual results to differ materially from those indicated by forward-looking statements are the risks and uncertainties described under "Risk Factors" in our other filings with the Securities and Exchange Commission ("SEC").

Forward-looking statements are expressly qualified in their entirety by this cautionary statement. The forward-looking statements included in this document are made as of the date of this document and we do not undertake any obligation to update forward-looking statements to reflect new information, subsequent events or otherwise.

#### PART I

#### ITEM 1 -BUSINESS

#### Overview of the Company

Simulations Plus, Inc., which was incorporated in California in 1996 ("Simulations Plus", or together with Words+, Inc. ("Words+") its wholly owned subsidiary referred to as the "Company," "us," "we," or "our"), develops and produces softw for use in pharmaceutical research and for education, as well as providing contract research services to the pharmaceutical industry. Simulations Plus has also taken over responsibility for producing a personal productivity software program called Abbreviate!, originally spun out of products for the disabled by Words+ for the retail market. Words+, which was incorporated in California in 1981, produces computer software and specialized hardware for use by persons with disabilities. For the purposes of this document, we sometimes refer to the two businesses as "Simulations Plus" when referring to the business of pharmaceutical software and services, educational software, and Abbreviate!, and "Words+" when referring to the business that is focused on assistive technologies for persons with disabilities. However, Simulations Plus has entered into a stock purchase agreement with the Prentke Romich Company of Wooster, Ohio ("PRC") to sell all of Simulations Plus' shares of Words+ to PRC. The anticipated closing of the sale of Words+ to PRC is November 30, 2011. Thus, if the sale transaction closes as anticipated, Words+ will be treated as "discontinued operations" going forward. See Note 11: Subsequent Events under the Notes to the Financial Statements included in this Annual Report on Form 10-K for more information.

#### Simulations Plus

#### **PRODUCTS**

We currently offer five software products for pharmaceutical research: ADMET Predictor<sup>TM</sup>, MedChem Studio<sup>TM</sup>, MedChem Designer<sup>TM</sup>, DDDPlus<sup>TM</sup>, and GastroPlus<sup>TM</sup>.

#### ADMET Predictor<sup>TM</sup>

Every drug molecule that fails in clinical trials, and every approved drug that gets withdrawn from the market, was doomed to fail from the time its structure was first drawn by a chemist or generated by a computer - they do not become bad later in development. The enormous resources that were required to bring these drugs to human trials and sometimes to market are wasted. Thus, the ability to predict unsuitable characteristics of new molecules as early as possible offers the promise of avoiding costly programs that end up as late-stage failures. Although not every failure mode can be predicted in this manner, those that can provide a means to reduce the number of failures that frequently occur after years of work and sometimes more than a billion dollars have been spent.

ADMET (Absorption, Distribution, Metabolism, Excretion and Toxicity) Predictor provides a collection of highly sophisticated and statistically significant numerical models that predict various properties of chemical compounds from just their molecular structures. Our models are built using proprietary machine learning approaches that are based primarily on artificial neural network ensembles (groups of artificial neural networks).

The vast majority of drug-like molecules are not suitable as medicines for various reasons. Some have such low solubility that they will not dissolve well, some have such low permeability through cell walls that they will not be absorbed well, some degrade so quickly that they are not stable enough to have a useful shelf life, some bind to proteins (such as albumin) in blood to such a high extent that little unbound drug is available to reach the target, and many will produce a variety of adverse effects. Identification of such properties in the computer ("in silico") enables researchers to rapidly eliminate poor compounds before spending time and money to make them and run experiments to identify their weaknesses. Today, many potential new molecules can be eliminated on the basis of the properties predicted by ADMET Predictor without the need to actually make and test them. We continue to add predictive models for additional properties to allow eliminating even more unsuitable molecules as early as possible.

Several independent studies have been published that compare the accuracy of software programs like ADMET Predictor. In almost every case, ADMET Predictor has been ranked first in accuracy. The specific set of molecules used in such studies, as well as the statistics used for comparison, often favors one program over others; however, across all published studies, ADMET Predictor has been top-ranked far more than any other program.

ADMET Predictor includes a subprogram called ADMET Modeler<sup>TM</sup> as an optional module. ADMET Modeler was first released in 2003 as a separate product (with the name QMPRchitect<sup>TM</sup>), and was integrated into ADMET Predictor in 2006. This powerful program is what we use to train our own best-in-class predictive models in ADMET Predictor. Having it available within ADMET Predictor means our users can train their own proprietary models using their own data for various properties and add them to the commercial models we provide. ADMET Modeler automates the complex training process, so very high quality models are produced in a small fraction of the time once required, and without the need for an expert modeler (although an expert modeler might achieve slightly better results). For example, new models are typically developed in a matter of a few minutes to a few hours once we complete the tedious effort of "cleaning up" the databases (which often contain a significant number of errors). Prior to the availability of ADMET Modeler, we needed as much as three months to develop each new model after cleaning the database.

Pharmaceutical companies spend enormous amounts of money conducting a wide variety of experiments on new molecules each year. Using their own proprietary data to build predictive models provides a second return on this investment; however, in the past, model-building has traditionally been a tedious activity performed by specialists. With ADMET Modeler integrated into ADMET Predictor, scientists without model-building experience can now use their own experimental data to quickly create high-quality predictive models.

ADMET Predictor is compatible with the popular Pipeline Pilot<sup>TM</sup> software offered by Accelrys, Inc. This software serves as a tool to allow chemists to run several different software programs in series to accomplish a set workflow for very large numbers of molecules. In early discovery, chemists often work with hundreds of thousands or millions of "virtual" molecules – molecules that exist only in computer files. Chemists need to decide which few molecules from these large "libraries" should be made and tested or taken further in development. Using Pipeline Pilot with ADMET Predictor (and MedChem Studio – see below), perhaps in conjunction with other software products, chemists can create and screen very large libraries faster and more efficiently than by running each program by itself. Perhaps the most important aspect of this process is obtaining sufficiently accurate property predictions for new molecular structures, so that molecules are not filtered out of the process that would have been successful as medicines, and molecules that cannot become useful medicines are eliminated from wasteful further development activities. Because of ADMET Predictor's accuracy, we believe we have a significant strategic advantage in this developing area of technology.

#### MedChem Studio<sup>TM</sup>

We have renamed our former ClassPharmer product to MedChem Studio to reflect the greatly enhanced capabilities it now has over the original acquired ClassPharmer product. MedChem Studio has become a powerful tool for medicinal and computational chemists both for data mining and for designing new drug-like molecules. Coupled with the accurate property predictions in ADMET Predictor, the two programs provide an unmatched capability for chemists to search through existing huge libraries of compounds to find the most promising classes and molecules that are active against a particular target. In addition, MedChem Studio with ADMET Predictor can take interesting (but not acceptable) molecules and very quickly generate high quality analogs (i.e., similar new molecules) using several different algorithms. The result is new molecules that are predicted to be both active against the target as well as acceptable in a variety of ADMET properties.

MedChem Studio's molecule design capabilities provide a number of ways for chemists to rapidly generate large numbers of novel chemical structures based on intelligence from compounds that have already been synthesized and tested, or from basic chemical reactions selected by the user. Export of results is available in Microsoft Excel® format as well as other convenient file formats requested by users.

#### MedChem Designer<sup>TM</sup>

Most chemists love to draw molecules. Molecule "sketchers" or drawing programs exist from several sources and are considered an essential part of the medicinal chemist's toolbox. Most of these programs are free, provided by their authors as a way to interface with other software. We launched MedChem Designer in February 2011 as a free program to help promote our ADMET Predictor and MedChem Studio products. MedChem Designer provides a highly intuitive interface for molecule sketching along with best-in-class property prediction from ADMET Predictor. We have made MedChem Designer an integral part of MedChem Studio, as well as a standalone product that can be downloaded and unlocked at no charge. The free version includes a small number of predicted properties from ADMET Predictor – basically, a way to introduce the power of combined molecule design with predicted properties that let the chemist quickly see the effects of changing molecular structures. Although a few properties are provided for free, the chemist can see that more than one hundred additional properties would be provided if they obtain a license for ADMET Predictor.

#### **DDDPlus**<sup>TM</sup>

Oral doses make up about 80% of all drug doses. Formulation scientists run many experiments in the lab to measure the rate at which new formulations (tablets and capsules) will dissolve. Doing this requires making the tablet or capsule, which consists of not only the active pharmaceutical ingredient ("API") but also a number of excipients that serve various purposes: to make a tablet strong enough to survive both manufacturing processes as well as shipping without crumbling; glidants to promote the flow of powders from source hoppers into tablet-making machines; lubricants for the machines; to control the surface behavior to make the table or capsule practical in a variety of environments with a wide range of temperature and humidity; and to make the API cost-effective to manufacture.

Often, meeting one requirement is at the cost of another. For example, increasing tablet strength can result in slower dissolution. Slower dissolution can be a disadvantage if the drug cannot be absorbed and get into the blood to do its job. Often, formulation design is an iterative process of making tablets or capsules, testing them, analyzing the results, cleaning up the manufacturing equipment and test lab, then doing it again and again until a suitable formulation is achieved.

DDDPlus simulates the in vitro laboratory experiments that measure the rate of dissolution of the drug contained in tablets and capsules in a variety of experimental conditions. This one-of-a-kind software program is used by formulation scientists to reduce the number of cut-and-try attempts to design new drug formulations, as well as to design in vitro experiments to better mimic in vivo conditions. During 2011, improvements were added to further enhance the value of this product, including numerous user convenience features, as well as more sophisticated handling of dosage forms that incorporate multiple polymers for controlled release formulations. The Food and Drug Administration (FDA) and a growing number of companies use DDDPlus in their work.

#### GastroPlus<sup>TM</sup>

GastroPlus is our flagship product, producing about 65% of our pharmaceutical software and services revenues. It simulates the absorption, pharmacokinetics, and pharmacodynamics of drugs administered to humans and animals, and is currently in use at numerous pharmaceutical companies, the FDA, and other government agencies in the U.S. and other countries.

At an international conference in Shanghai, China, in 2008, Pfizer scientists presented a scientific poster describing a two-year study in which all four commercially available PBPK (physiologically based pharmacokinetics) simulation programs were compared for their ability to predict human pharmacokinetics from preclinical (animal and in vitro) data. The study was divided into two arms: intravenous and oral dosing. GastroPlus was ranked first in both arms. No other software was ranked consistently in the top three.

The insight gained through GastroPlus simulations can guide project decisions in various ways. Among the kinds of knowledge gained through such simulations are: (1) the best estimate for "first dose in human" for a new drug prior to Phase I trials, (2) whether a potential new drug compound is likely to be absorbed at high enough levels to achieve the desired blood concentrations needed for effective therapy, (3) whether the absorption process is affected by certain enzymes and transporter proteins in the intestinal tract that may in turn affect the amount of drug reaching the blood, (4) when certain properties of a new compound are probably adequately estimated by in silico predictions (such as from ADMET Predictor) or from simple experiments, rather than through more expensive and time-consuming in vitro or animal experiments, (5) what the likely variations in blood and tissue concentration levels of a new drug would be in a large population, in different age groups or in different ethnic groups, and (6) whether a new formulation for an existing approved drug is likely to demonstrate "bioequivalence" (equivalent blood concentration versus time) to a currently marketed dosage form in a human trial (important for generic drug companies and the Office of Generic Drugs at the FDA).

Our marketing intelligence and reorder history indicate that GastroPlus continues to dominate its market niche in the number of users worldwide. In addition to virtually every major pharmaceutical company, licenses include government agencies in the U.S and abroad, a growing number of smaller pharmaceutical and biotech companies, generic drug companies, and drug delivery companies (companies that design the tablet or capsule for a drug compound that was developed by another company). Although these companies are smaller than the pharmaceutical giants, we believe they can also save considerable time and money through simulation. We believe this part of the industry, which we believe includes a few thousand companies, represents major growth potential for GastroPlus. Our experience has been that the number of new companies adopting GastroPlus continues to grow steadily, adding to the base of annual license renewals each year. Recent consolidations by larger companies have not affected our sales to date. In fact, because of the increased need for improving productivity, those companies have typically adopted in silico tools at ever-greater levels, with the result that large company licenses have typically increased at renewal time even in the face of such consolidation.

#### Contract Research and Consulting Services

Our recognized world-class expertise in oral absorption and pharmacokinetics is evidenced by the fact that our staff members have been speakers or presenters at approximately 75 prestigious scientific meetings worldwide in the past two years. We frequently conduct contracted studies for large customers (including top 5 pharmaceutical companies) who have particularly difficult problems and who recognize our expertise in solving them, as well as for smaller customers who prefer to have studies run by our scientists rather than to license our software and train someone to use it. The demand for our consulting services has been increasing steadily, and we expect this trend to continue. Long-term collaborations and shorter-term consulting contracts serve both to showcase our technologies and to build and strengthen customer relationships.

#### Government-Funded Research

We completed our Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH) during fiscal year 2011. This three-year effort led to the development of our rapid atomic partial charge calculations in ADMET Predictor, which in turn has led to the ability to predict metabolism and metabolic sites (i.e., which atoms on a molecule are likely to be attacked by certain enzymes). The result, we believe, is the most accurate prediction of metabolism and metabolic sites available today. This is expected to be released in ADMET Predictor Version 6.0

before the end of calendar year 2011.

#### PHARMACEUTICAL SOFTWARE PRODUCT DEVELOPMENT

Although all of our development work cannot be disclosed for competitive reasons, some of our development efforts during this reporting period included:

#### (1) ADMET Predictor/ADMET Modeler Upgrades

In February 2011, we released version 5.5 of ADMET Predictor with a number of new features:

- o A new Metabolite Module with 10 new models for sites of metabolism
  o An expanded Toxicity Module with 9 new models, extending the total number to over 30
  o An expanded Enslein Metabolism Module
  - o An expanded Physicochemical and Biopharmaceutical Properties Module
    o Expanded ADMET Risk<sup>TM</sup> capabilities for multiobjective molecule design optimization
    o Expanded ADMET Modeler<sup>TM</sup> model-building capabilities
    - o Enhanced graphics presentations for visualization of new calculated properties

We believe these new features enhance the value of ADMET Predictor for our pharmaceutical customers, project ADMET Predictor further into the markets for toxicity prediction, both environmental and pharmaceutical, and enhance the combination of our MedChem Studio<sup>TM</sup> data mining and molecule design software through the integration of ADMET Predictor with MedChem Studio and the new powerful ADMET Risk capabilities.

In version 6.0 of ADMET Predictor, which we expect to release before the end of calendar year 2011, we are adding a number of new models as well as revising the user interface to make the problem more flexible and friendly.

#### (2) MedChem Studio

We launched MedChem Studio 2.0 in April 2011 with:

Our new MedChem Designer advanced molecule drawing tool
 Greatly expanded multidimensional graphics output
 Enhanced import capabilities for molecular structure files
 Enhanced capabilities for exporting results
 Additional improvements to our industry-best structure depictions

With the MedChem Studio/MedChem Designer/ADMET Predictor combination, chemists now have the capability to see how changes in molecular structures affect not just one or a handful of properties, but over 130 properties from the industry's top-ranked property prediction program, ADMET Predictor. We believe that this represents the future for drug discovery and that no other technology offers as much potential for reducing the time and money required to discover new structures that can become tomorrow's medicines.

Ongoing developments are directed toward continued expansion of the program's molecule design and data mining capabilities, including enhanced plotting of multidimensional data to better enable chemists to see how various molecular structures are distributed with respect to a variety of molecular features and predicted properties from ADMET Predictor.

#### (3) MedChem Designer

MedChem Designer was launched in February 2011. This new product is provided free as a standalone program, as well as integrated into MedChem Studio.

Unique features of MedChem Designer include:

- Intuitive interface with many innovative features for molecular structure drawing and manipulation
- Several free predicted key molecular properties from our top-rated ADMET Predictor software
  - With a full ADMET Predictor license, a wide range of predicted properties:

o Physicochemical properties
o Pharmacokinetic parameters
o Cytochrome P450 (CYP) enzyme metabolism rates
o CYP inhibition
o Sites of CYP oxidation
o UGT metabolism
o Over 30 potential toxicities

o Partial atomic charges and reactivities based on our proprietary rapid quantum chemical descriptor calculations

#### (4) DDDPlus

DDDPlus 4.0 was launched in June 2011 with several enhancements:

Expanded Parameter Sensitivity Analysis
 New Virtual Trial capability
 New immediate release capsule dosage form
 Variety of enhanced input and output functions

#### (5) GastroPlus

Intensive development efforts have been ongoing in our flagship GastroPlus software during this fiscal year. These include expansion of the Drug-Drug Interaction Module to incorporate transporters as well as induction of both enzymes and transporters. This new capability completes the drug-drug interaction picture, allowing scientists to model all of the most common drug-drug interaction mechanisms that complicate dosing to patients with multiple medications. Most patients take more than one medication – some as many as 8-10 per day or more. When two or more drugs compete for the same enzymes or transporters, interactions can have a helpful or a harmful effect. The Drug-Drug Interaction Module in GastroPlus is designed to enable pharmaceutical scientists to analyze the potential for interactions before they occur, and to provide guidance for whether dosing regimens (how much of each drug and when) might need to be adjusted to either take advantage of helpful interactions or to avoid those that could cause adverse effects.

The PDPlus<sup>TM</sup> Module for modeling pharmacodynamic effects has undergone considerable enhancements, now allowing automatic fitting of all of its models to find the most appropriate mathematical form to describe pharmacodynamic effect (the effect of the drug on the body, as opposed to pharmacokinetic effect – the effect of the body on the drug).

A large number of other program enhancements have been in development and are expected to be released with the launch of version 8.0, currently expected in December 2011.

#### (6) MembranePlus<sup>TM</sup>

MembranePlus is a computer program that simulates in vitro experiments that measure the permeability of new drug-like molecules through a layer of living cells or through an artificial membrane. These experiments are conducted in order to estimate the permeability of new drug compounds through the cells lining the intestinal walls and other tissues of humans and various animals. However, such experiments often do not produce results that are easily translated into in vivo permeabilities. We believe that a detailed mechanistic simulation of such in vitro experiments can provide the insight and understanding needed to provide reasonably accurate estimates of permeability in different regions of human and animal tissues from in vitro data.

This development effort accelerated during fiscal year 2005 with the hiring of a new Ph.D. scientist who focused on this program. The simulation is currently predicting the movement of drug molecules from the bulk fluid, into the membranes at the surface of a cell layer, through the surface membrane, through the interior of the cell, into the opposite surface membrane, and through it to the bulk fluid on the opposite side of the cell layer. Although a few technical issues remain to be resolved, we are optimistic that the simulation can become a unique tool for the analysis of data from these experiments, and can enable researchers to more accurately estimate human intestinal permeability from these in vitro experiments.

This project was put on hold in late 2005 because the scientist responsible for MembranePlus, Dr. Viera Lukacova, was assigned to take over GastroPlus when the previous product manager left the company. New additions to the Simulation Technologies Team are currently working on GastroPlus version 8.0, but we expect one will be assigned to work on MembranePlus after GastroPlus 8.0 is released.

#### MARKETING AND DISTRIBUTION

We market our pharmaceutical software and consulting services through attendance and presentations at scientific meetings, exhibits at trade shows, seminars at pharmaceutical companies and government agencies, through our web pages on the Internet, and using various communication media to our compiled database of prospect and customer names. At the American Association of Pharmaceutical Scientists (AAPS) conference in Washington, D.C., in October 2011, there were twenty different presentations and posters presented in which the research that was reported was done using GastroPlus. Fifteen of those were from industry and FDA scientists, five were from our staff.

In recent months we added an independent sales representative in Europe, and we have two independent representatives in China; however, our scientific team is also the majority of our sales and marketing team, assisting our Director of Marketing and Sales with trade shows, seminars, and customer training both via Internet and on-site. We believe that this is more effective than a completely separate sales team for several reasons: (1) customers appreciate talking directly with developers who can answer a wide range of technical questions about methods and features, (2) our scientists benefit from direct customer contact by gaining an appreciation for the environment and problems of the customer, and (3) the relationships we build through scientist-to-scientist contact are stronger than through salesperson-to-scientist contacts.

We use the Internet to provide product information and software updates, and as a forum for user feedback and information exchange. We have cultivated market share in North America, South America, Europe, Australia, New Zealand, Singapore, People's Republic of China, and Japan, and Internet and e-mail technologies have had a positive influence on our ability to communicate with existing and potential customers worldwide.

#### **PRODUCTION**

Our pharmaceutical software products are designed and developed entirely by our development team in California, with locations in Lancaster, Petaluma, San Jose, and San Diego. The principal materials and components used in the manufacture of simulation software products include CD-ROMs and instruction manuals, which are also produced in-house and through outside contractors. In-house graphic art and engineering talent enables us to accomplish this production in a cost-efficient manner.

#### **COMPETITION**

In our pharmaceutical software and services business, we compete against a number of established companies that provide screening, testing and research services, and products that are not based on simulation software. There are also software companies whose products do not compete directly, but are sometimes closely related. Our competitors in this field include some companies with financial, personnel, research and marketing resources that are greater than ours. Management believes there is currently no significant competitive threat to GastroPlus or DDDPlus, however, one could be developed in time. MedChem Studio and ADMET Predictor/ADMET Modeler operate in a more competitive environment. Several other companies presently offer simulation or modeling software, or simulation-software-based services, to the pharmaceutical industry.

Major pharmaceutical companies conduct drug discovery and development efforts through their internal development staffs and through outsourcing some of this work. Smaller companies need to outsource a greater percentage of this research. Thus, we compete not only with other software suppliers, but also with the in-house development teams at some of the larger pharmaceutical companies.

Although competitive products exist, both new licenses and license renewals for GastroPlus have continued to grow in spite of this competition. We believe that we enjoy a dominant market share in this segment.

We believe the key factors in competing in this field are our ability to develop industry-leading simulation and modeling software and related products and services to effectively predict activities and ADMET-related behaviors of new drug-like compounds, to design new molecules with acceptable activity and ADMET properties, to develop and maintain a proprietary database of results of physical experiments that will serve as a basis for simulated studies and empirical models, to attract and retain a highly skilled scientific and engineering team, and to develop and maintain relationships with research and development departments of pharmaceutical companies, universities and government agencies.

We are actively seeking acquisitions to expand the pharmaceutical software and services business. Earlier attempts to acquire other companies have not been successful either in arriving at mutually agreeable terms and conditions, or because of adverse conditions discovered during our comprehensive due diligence process.

#### WORDS+

#### **PRODUCTS**

Our wholly owned subsidiary, Words+, has been focused on introducing and improving augmentative and alternative communication and computer access software and devices for people with disabilities for over 30 years. The introduction of EyeProTM, an eyegaze product, in 2010 increased our revenue and marketshare. Eyegaze technology allows people to operate a computer or communication device by simply looking at the screen, and has been a major breakthrough for people with severe disabilities. In 2011, we added the EyePro GS to our eyegaze product line. The EyePro GS uses proprietary technology developed by Words+, where our other EyePro products use third party eyegaze technology that we bundle into our products. EyePro GS was released near the end of FY 2011. We also introduced the Conversa CV and CVX and upgraded most products to Windows 7. The Conversa is our line of tablet-based communication devices. The Conversa CV and CVX are based on Windows tablets with flip screens that allow them to convert between tablet and notebook formats.

#### MARKETING AND DISTRIBUTION

We market augmentative and alternative communication products through a network of employee representatives and independent dealers and resellers. Webinars and remote interaction using web-based evaluation, setup and training, introduced in 2009, have become standard parts of our operation. We have continued to see an increase in the number of family members, caregivers, teachers, and aides attending the live and recorded webinars. This is a significant change in the speech pathologist-to-patient relationship, and allows the speech pathologists' professional experience and advice to extend beyond the therapy session to achieve more effective results for their clients. It has also allowed our sales force to spend less time training and more time selling, and allows us to recruit, train and support resellers who are less experienced in assistive technology.

We currently have 33 sales representatives worldwide: 1 salaried sales manager, 11 independent distributors and 6 independent resellers in the U.S., and 15 sales representatives overseas – 3 in Australia, and 1 each in New Zealand, Canada, The Netherlands, France, Ireland, Italy, Israel, Japan, Korea, Mexico, Malaysia, and Taiwan. We also have 3 inside support persons, who answer e-mails and telephone inquiries on our toll-free telephone line and who provide customer and technical support. Additional outside salespersons and independent dealers and resellers are being actively recruited.

We direct our marketing efforts to speech pathologists, occupational therapists, rehabilitation engineers, special education teachers, disabled persons and relatives of disabled persons. We maintain a mailing list of over 10,000 people made up of these professionals, consumers and relatives, and we mail various marketing materials to this list. These materials include our catalog of products and announcements regarding new and enhanced products.

We participate in industry conferences held worldwide that are attended by speech pathologists, occupational and physical therapists, special education teachers, parents and consumers. We and others in the industry demonstrate our products at these conferences and present technical papers that describe the application of our technologies and research studies on the effectiveness of our products. Words+ attended five major national conferences in 2011, and several more specialized national conferences, such as TEDPA (the national conference for specialized telecommunication equipment distribution program) and the American Occupational Therapist Association national conference. We responded to calls for papers and presented five different professional sessions during these conferences. We also advertise in selected publications and websites of interest to persons in this market.

We estimate that for approximately 62% of our sales of augmentative and alternative communication ("AAC") software and hardware, purchases are funded primarily by third parties such as Medicaid, Medicare and private insurance. Telecommunication equipment distribution programs, school special education budgets, vocational rehabilitation, the Veterans Administration and other governmental programs, private purchases and charitable assistance account for most of the other purchases. Medicare provides coverage for augmentative communication devices.

Our personnel provide advice and assistance to customers and prospective customers on obtaining third-party financial assistance for purchasing our products. Third-party funding grew slowly for the first 20 years of operation; however, the addition of Medicare coverage for AAC devices in 2001 resulted in significant increases in third-party funding in recent years. Our Medicare/Medicaid and other third-party-funded sales have grown, with the majority of total sales are now funded by a third party. Medicare/Medicaid sales are subject to funding caps that limit the amounts paid for our products, and payment by some agencies can be slow, making this market segment somewhat more difficult than others. Collection of accounts receivable has been a significant problem from certain state Medicaid agencies, Medicaid, and private insurance. Our financial reporting includes allowances for bad debts that are based on assumptions that we will collect a historical percentage of accounts receivable that fall in different aging categories: less than 6 months, 6-12 months, 12-24 months, and over 24 months. Although we may not give up on any of the invoices that are included in the allowances for bad debts, we recognize that responsible financial reporting

requires us to be conservative in these estimates.

#### **PRODUCTION**

Disability software products are either loaded onto computer hard disk drives by our employees or copied to CD-ROM or memory cards. Most software customers also buy their notebook personal computers from us, which we purchase at wholesale prices and resell at a markup. We purchase microprocessors that are part of dedicated devices such as MessageMates<sup>TM</sup>. We design our cases, printed circuit boards, labels and other components of products such as SAM Communicator<sup>TM</sup> and our popular Conversa<sup>TM</sup> Sound Pack. We outsource the extrusion, machining and manufacturing of certain components. All final assembly and testing operations are done by our employees at our facility.

Our products are shipped from our Lancaster, California facility either directly to the customer or to the salesperson, dealer or reseller. Historically for major products, the outside salesperson, dealer or reseller either delivers the product or visits the customer after delivery to provide training. In our remote interactive sales and delivery model, an increasing number of deliveries are being completed utilizing internet with video support for setup, and webinars plus individual live video interaction for training.

#### **COMPETITION**

The AAC industry in which we operate is highly competitive and some of our competitors have greater financial and personnel resources than ours. The industry is made up of about six major competitors including Words+, and a number of smaller ones. Following the introduction of EyePro and other products to complement our current catalog, we are now focused on developing new products in-house.

We believe that the competition in this industry is based primarily on the quality of products, quality of customer training and technical support, and quality and size of sales forces. Price is a competitive factor that has traditionally not been as important to the purchaser or recommender as obtaining the product most suited to the customer's needs, along with strong after-sale support. However, there has been significant downward pricing pressure due to the increasing popularity of extremely low-priced communication apps available on the popular Apple iPod and iPad, particularly in the past year. This is a change in our industry leading to a new category of low-cost technology, private payers, different service delivery expectations, and adverse affects on some traditional purchasers such as schools. To meet this challenge, we have been exploring lower cost solutions that compete in the iPod and iPad space, and different pricing and payment options to add to the cost-cutting, web-based remote delivery, training and support services we began in 2009. This remains a significant challenge and opportunity for us that we will continue to focus on.

We believe that we are a leader in the industry in developing and producing some of the most technologically advanced products and in providing quality customer training and technical support. We believe that the potential exists for significant increases in the sales of our disability products; however, there are few barriers to entry in the form of proprietary or patented technology or trade secrets in this industry. While we believe that cost of product development and the need for specialized knowledge and experience in this industry would present some barrier to entry for new competition, other companies may enter this industry, including companies with substantially greater financial resources than ours. Furthermore, companies already in this industry may increase their market share through increased technology development and marketing efforts.

#### TRAINING AND TECHNICAL SUPPORT

Customer training and technical support are important factors in customer satisfaction for both our pharmaceutical and disability products, and we believe we are an industry leader in providing customer training and technical support in both of our business areas. For pharmaceutical software, we provide in-house seminars at customers' sites. These seminars often serve as initial training in the event the potential customer decides to license or evaluate our software. Technical support is provided after the sale in the form of on-site training (at customer's expense), web

meeting, telephone, fax, and e-mail assistance to users during the customer's license period. We have used Internet meetings extensively to provide demonstrations and customer assistance, resulting in rapid response to requests worldwide and reducing our travel time and expenses.

For disability products, our salesperson, dealer or reseller historically provided initial training to the customer for major systems -- typically two to four hours. This training is typically provided not only to the user of the product but also to speech pathologists, occupational therapists, rehabilitation engineers, teachers, parents and others who will assist the user. This initial training for the purchase of full systems is often provided as a part of the price of the product. Additional training and service calls are available for a fee. Live and recorded webinars introduced last year have significantly changed our service delivery model, making it more accessible to people who need training, and reducing the amount of time our sales force spends traveling and providing on-site, one-on-one training and support. Our salespeople still visit in person whenever appropriate, but the professional on-line training and support have greatly reduced this need. Feedback from surveys and increasing webinar attendance indicate improved customer satisfaction with our products and service delivery. The remote service delivery model that we have already implemented is becoming an expectation in our industry.

Technical support for both pharmaceutical software and disability products is provided by our life sciences team and our inside sales and support staff based at our headquarters facilities in Lancaster, California. We provide free telephone support offering unlimited toll-free numbers in the U.S. and Canada, and e-mail and web-based support for all of our pharmaceutical software and disability products worldwide. Technical support for pharmaceutical software products is minimal, averaging a few person-hours per month. Technical support for Words+ products varies from none for most customers to as much as several hours for others.

#### RESEARCH AND DEVELOPMENT

We believe that our ability to grow and remain competitive in our markets is strongly dependent on significant investment into research and development ("R&D"). R&D activities include both enhancement of existing products and development of new products. Development of new products and adding functionality to existing products are capitalized in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 985-20. R&D expenditures were approximately \$1,846,000 during fiscal year 2011, of which \$911,000 was capitalized. R&D expenditures during fiscal year 2010 were approximately \$1,857,000, of which \$887,000 was capitalized.

Our pharmaceutical business R&D activities during fiscal year 2011 were focused on improving our ADMET Predictor/ADMET Modeler, MedChem Studio, MedChem Designer and GastroPlus products.

Our R&D activities for our Words+ subsidiary were focused on development of our new EyePro GS eye gaze product line, extension of the family of tablet-computer-based systems called Conversa, and two new hardware development projects that we are not ready to announce at this time.

#### **EMPLOYEES**

As of August 31, 2011, we employed 38 full-time and 1 part-time employees, including 20 in research and development, 5 in marketing and sales, 8 in administration and accounting and 6 in production. Currently 16 employees hold Ph.D.s and 1 is a Ph.D. candidate in their respective science or engineering disciplines. Additionally, 3 employees hold one or more Master's degrees. Most of the senior management team and Board of Directors hold graduate degrees. We believe that our future success will depend, in part, on our ability to continue to attract, hire and retain qualified personnel. The competition for such personnel in the pharmaceutical industry and in the augmentative and alternative communication device and computer software industry is intense. None of our employees is represented by a labor union, and we have never experienced a work stoppage. We believe that our relations with our employees are good. As noted earlier, we have signed an agreement to sell our Words+ subsidiary and expect to complete the transaction by November 30, 2011. After that date, assuming the transaction is completed, our number of employees will be reduced to approximately 25, of which all but four have advanced degrees. We continue to seek additions to our Life Sciences team.

#### **PATENTS**

We own two patents that were acquired as part of our acquisition of certain assets of Bioreason, Inc. We primarily protect our intellectual property through copyrights and trade secrecy. Our intellectual property consists primarily of source code for computer programs and data files for various applications of those programs in both the pharmaceutical software and the disability products businesses. In the disability products business, electronic device schematics, mechanical drawings, and design details are also intellectual property. The expertise of our technical staff is a considerable asset closely related to intellectual property, and attracting and retaining highly qualified scientists and engineers is essential to our business.

#### EFFECT OF GOVERNMENT REGULATIONS

Our pharmaceutical software products are tools used in research and development and are neither approved nor approvable by the FDA or other government agencies.

Most of our Words+ products for the disabled are funded by Medicare or Medicaid, schools, the Veteran's Administration, and other insurance programs. Changes in government regulations regarding the allowability of augmentative communication aids and other assistive technology under such funding could affect our business; however, as noted earlier, Words+ is expected to be sold by November 30, 2011.

#### Costs and Effects of Compliance with Environmental Laws

Federal, state and local laws and regulations regarding the discharge of harmful materials into the environment may have an impact on the Company. Words+ is involved in manufacturing of Augmentative Communication Devises which uses laptop computers, and minor electronic assembly that might have a material adverse effect on the environment. However, the Company's exposure to environmental laws is not expected to be any more significant than any other similar type of business. Any new laws or regulations with regard to the environment that affect businesses in general are likely to result in additional compliance costs, and could result in additional operating restrictions. These costs could affect our future business operations. Words+ incurred environmental fee of \$288 and \$292 in FY11 and FY10, respectively, and electronic waste recycling fee of \$466 and \$16 in FY11 and FY10, respectively.

#### ITEM 1A - RISK FACTORS

Not applicable because the Company is a smaller reporting company.

#### ITEM 1B - UNRESOLVED STAFF COMMENTS

Not applicable.

#### ITEM 2 - PROPERTIES

We lease approximately 13,500 square feet of space in Lancaster, California. The original agreement had a five-year term with two (2), three-(3) year options to extend. Since the original five-year term expired in February 2011, we have exercised the first of the two (2), three-year options. The base rent started at the rate of \$18,445 per month plus common area maintenance fees. The base rental rate increases at 4% annually and currently it is \$21,578 per month, plus common area maintenance fees. We believe that this facility is sufficient for our current needs and growth for the foreseeable future.

In connection with the sale of our Words+ subsidiary to Prentke Romich Company, we expect to temporarily lease a portion of this space to PRC on a prorated basis. After January 1, 2012, we expect that portion to be reduced, providing additional room for growth of the Simulations Plus staff, which has been reaching its limits within the space available prior to the pending sale of Words+.

#### ITEM 3 – LEGAL PROCEEDINGS

The Company is not a party to any legal proceedings and is not aware of any pending legal proceedings of any kind.

ITEM 4 – [REMOVED AND RESERVED]

#### PART II

## ITEM 5 – MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock is currently traded on the NASDAQ Stock Market (NASDAQ) under the symbol "SLP". According to the records of our transfer agent, we had approximately 56 shareholders of record and approximately 1,540 beneficial owners as of August 31, 2011. The following table sets forth the low and high sale prices for our Common Stock as listed on the NASDAQ for the last two fiscal years. We have not paid cash dividends on our Common Stock to date. Any determination as to the payment of dividends will be at the discretion of our Board of Directors and will depend among other things, on our financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

On October 23, 2008, our board of directors authorized a share repurchase program enabling the buyback of up to \$2.5 million in shares during a 12-month period beginning Monday, October 27, 2008. The actual repurchase started on December 2, 2008; therefore the board of directors extended it through December 1, 2009 in order to have a full 12-month period. The Company opened an account with Morgan Stanley Smith Barney for the purchase of such securities. Funds for any stock purchases are drawn from the Company's cash reserves. The Company repurchased 1,026,483 shares at an average price of \$1.3823 per share prior to December 1, 2009.

On January 10, 2010, the board of directors authorized a second share repurchase program (Phase II) effective as of February 15, 2010. The renewed program enabled the Company to buy back up to one million shares during a 12-month period. Under the Phase II program, the Company has purchased 996,248 shares at an average price of \$2.8041 per share from April 2010 to February 2011.

There is currently no share repurchase program pending, and the Company made no repurchases of its securities within the fourth quarter of the fiscal year covered by this report.

The following table shows low and high sales price for the last eight fiscal quarters.

	Low Sales	High Sales
	Price	Price
FY11:		
Quarter ended August 31, 2011	2.76	3.47
Quarter ended May 31, 2011.	2.68	3.27
Quarter ended February 28, 2011	2.42	3.69
Quarter ended November 30, 2010	2.40	3.50
FY10:		
Quarter ended August 31, 2010	2.04	2.52
Quarter ended May 31, 2010	1.67	2.50
Quarter ended February 28, 2010	1.35	1.72
Quarter ended November 30, 2009	1.32	1.79

#### **EQUITY COMPENSATION PLAN INFORMATION**

The following table provides a summary of Equity Compensation Plan Information.

#### Equity Compensation Plan Information (1)

		Number of securities
		remaining available for
		future
Number of securities	Weighted-average	issuance under equity
to be issued upon	exercise	compensation
exercise of outstanding	price of outstanding	plans (excluding
options,	options,	securities
warrants and rights	warrants and rights	reflected in column (a))
(a)	(b)	(c)
957,636	\$ 1.39	412,000
0	0	0
U	U	U
957,636		412,000
	to be issued upon exercise of outstanding options, warrants and rights (a)  957,636	to be issued upon exercise of outstanding options, warrants and rights (a)  957,636  \$ 1.39

- (1) The Company is authorized to issue stock options under the following compensation arrangement:
  - a. 4,000 shares per year per person to Directors as a part of their annual stipends.

b.50 shares for each \$1,000 of net income before taxes at the end of each fiscal year (up to a maximum of 120,000 options) to CEO over the term of his current employment agreement

#### ITEM 6 – SELECTED FINANCIAL DATA

Not applicable because the Company is a smaller reporting company.

## ITEM 7 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and related notes included in this Annual Report on Form 10-K.

#### Management Overview

Fiscal year 2011 was a record year comprised of three record quarters. We believe the continued growth of our pharmaceutical software and services business segment is the result of increasing adoption of simulation and modeling software tools such as those we produce, as well as the expertise we offer as consultants to assist companies involved in the research and development of new medicines, which has resulted in a continuing series of study contracts with pharmaceutical companies ranging from several of the largest in the world to a number of medium-sized and smaller

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companies in the U.S. and Europe.

During FY11 we released major upgrades to three of our four pharmaceutical software offerings, and a new software product called MedChem Designer. Our financial performance enabled us to continue to increase our cash deposits, remain debt-free, and continue to invest in the aggressive marketing and sales activities we began in early 2009 in order to reach a wider customer base.

We have not been successful in identifying and completing any acquisitions during this reporting period in spite of a number of investigations and due diligence activities. In every case, either our due diligence activities revealed undesirable aspects of the potential acquisition, or terms and conditions agreeable to both sides were not able to be reached. It is our intent to continue to search for acquisition opportunities that would be compatible with our current businesses and that would be immediately accretive, i.e., adding to both revenues and earnings.

We have used some of our cash to repurchase shares of our common stock because we believe that reducing the number of fully diluted shares provides greater value to our shareholders than receiving a low interest rate on our cash deposits, and because we believe that our cash deposits after such repurchases remain sufficient to accomplish any reasonable potential acquisitions as well as to maintain sufficient cash reserves to ensure meeting operational needs for the foreseeable future. Although there are no stock repurchase programs pending, the board of directors may consider additional repurchases at any time at prices and under conditions set by the board.

Our Words+ subsidiary's net income increased despite of the decline in sales due to reducing expenses. We developed and released our own new EyePro eyegaze system in August 2011; however, the continued poorer performance of this business unit caused us to agree to sell Words+ in November 2011, as previously discussed.

If the sale of Words+ is closed in November 2011, its net sales and income will be reported as discontinued operations going forward. The net sales and income for the last 3 years of Words+ operations are followings.

				Net			
			In	come (or			
	]	Net Sales		loss)			
FY09	\$	2,842,000	\$	(87,000)			
FY10		3,091,000		(82,000)			
FY11		2,981,000		72,000			

#### **Results of Operations**

The following sets forth selected items from our statements of operations (in thousands) and the percentages that such items bear to net sales for the fiscal years ended August 31, 2011 ("FY11") and August 31, 2010 ("FY10").

		FY11			FY10	
Net sales	\$ 11,720		100.0%	\$ 10,712		100.0%
Cost of sales	2,879		24.6	2,546		23.8
Gross profit	8,841		75.4	8,166		76.2
Selling, general, and administrative	4,305		36.7	4,325		40.4
Research and development	935		8.0	970		9.1
Total operating expenses	5,240		44.7	5,295		49.5
Income from operations	3,601		30.7	2,871		26.7
Interest income	92		0.8	101		0.9
Interest expense	-		-	(1	)	(0.0)
Miscellaneous Income	1		0.0	1		0.0
Gain on sale of assets	-		-	2		0.0
Gain on currency exchange	76		0.6	130		1.2
Total other income	169		1.4	233		2.1
Net income before taxes	3,770		32.2	3,104		28.8

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Provision for income taxes	(1,055	)	(9.0	)	(948	)	(8.8)	)
Net income	2,715		23.2%		2,156		20.0%	
17								

#### FY11 COMPARED WITH FY10

#### Net Sales

Consolidated net sales increased \$1,008,000, or 9.4%, to \$11,720,000 in FY11 from \$10,712,000 in FY10. Sales from pharmaceutical software and services increased approximately \$1,118,000, or 14.7%; while Words+'s sales decreased approximately \$110,000, or 3.6%, for the year. We attribute the increase in pharmaceutical software sales to increases in the number of licenses with new and existing customers, as well as licensing of new modules to existing customers. In addition, we generated revenue from workshop programs which we started in FY11. Those increases outweighed the decreases in revenue from funded collaborations and analytical studies (large collaboration contacts were completed by August 2010) and Grant (2-year grant from NIH ended at March 2011). We attribute the decrease in Words+ sales to a decline in sales of the "Say-it SAM!" handheld communicator competing against cheaper iPhone and iPad products which fit under the funding cap of some agencies, and to a decline in sales of hardware products. Decreased revenue from these products outweighed increases in revenue from our Freedom2000, "Conversa", and our new EyePro products.

#### Cost of Sales

Consolidated cost of sales increased \$333,000, or 13.1%, to \$2,879,000 in FY11 from \$2,546,000 in FY10. As a percentage of revenue, cost of sales also increased by 0.8%. For pharmaceutical software and services, cost of sales increased \$286,000, or 23.6%, and as a percentage of revenue, it also increased to 17.1% in FY11 from 15.9% in FY10. A significant portion of cost of sales for pharmaceutical software products is the systematic amortization of capitalized software development costs, which is an independent fixed cost rather than a variable cost related to sales. This amortization cost increased approximately \$64,000, or 11%, in FY11 compared with FY10. Royalty expense, another significant portion of cost of sales, increased approximately \$134,000, or 30%, and Salary for analytical study increased approximately 88,000, or 50%, in FY11 compared with FY10. We pay a royalty on GastroPlus basic software sales but not on its optional modules. We also pay royalties on the Enslein Metabolism Module in our ADMET Predictor software in accordance with our agreement with Enslein Research, Inc.

For Words+, cost of sales increased \$47,000, or 3.6%, and as a percentage of revenue, cost of sales also increased to 46.3% in FY11 from 43.1% in FY10.

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#### **Gross Profit**

Consolidated gross profit increased \$675,000, or 8.3%, to \$8,841,000 in FY11 from \$8,166,000 in FY10. We attribute this increase to increased sales of pharmaceutical software and services which outweighed the decline in gross profit from Words+ operations.

#### Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses for FY11 decreased by \$20,000, or 0.5%, to \$4,305,000, compared to \$4,325,000 for FY10. As a percentage of sales, SG&A expenses decreased to 36.7% in FY11 from 40.4% in FY10. For Simulations Plus, SG&A expenses increased \$273,000, or 10.6%. As a percentage of sales, SG&A for Simulations Plus decreased to 32.5% from 33.7%. The major increases in expenses were sales commissions as revenue from Japan and China increased, bonus expense paid to our CEO per his employment agreement, consulting fees, cost associated with stock repurchases, and payroll with payroll-related expenses, such as health/dental insurances and payroll taxes which outweighed the decrease in professional fees.

For Words+, expenses decreased by \$293,000, or 16.7% due to decreases in allowances for bad debts.

#### Research and Development

We incurred approximately \$1,846,000 of research and development ("R&D") costs during FY11. Of this amount, \$911,000 was capitalized and \$935,000 was expensed as R&D. As we record hours spent for studies, \$262,000 was expensed as cost of sales. During FY10, we incurred approximately \$1,857,000 of research and development costs, of which approximately \$887,000 was capitalized and approximately \$970,000 was expensed. The hours spent for studies during FY10 expensed as cost of sales amounted to \$175,000. The 0.6% decrease in research and development expenditure from FY10 to FY11 was due to an increase in hours spent on analytical studies, which reduced hours available for R&D activities.

#### Income from operations

During FY11, we generated income from operations of \$3,601,000, as compared to \$2,871,000 for FY10, an increase of 25.4%. We attribute this increase to increases in gross profit from pharmaceutical software and study contract services and decreases in SG&A expense and R&D expenses.

#### Other Income and (Expense)

The net of other income over other expense for FY11 decreased by \$64,000, or 27.6%, to \$169,000, compared to \$233,000 for FY10, due to changes in the currency exchange rate for Japanese Yen caused by the weaker U.S. dollar.

#### **Provision for Income Taxes**

Provision for income taxes for FY11 increased by \$107,000, or 11.3%, to \$1,055,000, compared to \$948,000 for FY10 due to the increase in net income. The tax rate used in this report is lower than the standard rate because of various tax credits generated during this reporting period.

#### Net Income

Net income for FY11 increased by \$559,000, or 25.9%, to \$2,715,000, compared to \$2,156,000 for FY10. We attribute this increase in net income to increased gross profit, decreases in SG&A and R&D expenses, which outweighed decreases in other income and an increase in taxes.

#### **SEASONALITY**

Sales in the pharmaceutical products and services business segment ("Simulations Plus" in the table below) exhibit some seasonal fluctuations, with the fourth fiscal quarter (June-August) generally having the lowest sales over the past three fiscal years because of summer vacations and reduced activities at our customers' sites. This unaudited net sales information has been prepared on the same basis as the annual information presented elsewhere in this Annual Report on Form 10-K and, in the opinion of management, reflects all adjustments (consisting of normal recurring entries) necessary for a fair presentation of the information presented. Net sales for any quarter are not necessarily indicative of sales for any future period; however, because our pharmaceutical software is licensed on an annual basis, renewals are almost always within the same quarter year after year.

	Net Simulations Plus Sales (in thousands)				
	First	Second	Third	Fourth	
FY	Quarter	Quarter	Quarter	Quarter	Total
2011	2,050	2,622	2,640	1,427	8,739
2010	1,735	2,227	2,325	1,334	7,621
2009	1,430	1,779	1,985	1,107	6,301
2008	1,438	1,550	1,975	1,092	6,055
2007	824	1,808	1,659	1,465	5,756
2006	199	884	1,096	1,007	3,186
2005	524	410	662	473	2,069
2004.	642	742	603	869	2,856
2003	507	582	614	1,403	3,106
2002	390	554	504	595	2,043
2001	221	373	305	282	1,181
2000	151	467	143	174	935
1999	87	93	117	164	461
1998	11	11	13	27	62

Sales of our disability products business segment ("Words+") to schools were slightly seasonal prior to our fiscal year ended August 31, 2006, with greater sales to schools during our third and fourth fiscal quarter (March-May and June-August), as shown in the table below.

	First	Second	Third	Fourth	
FY	Quarter	Quarter	Quarter	Quarter	Total
2011	761	728	799	693	2,981
2010	702	723	794	872	3,091
2009	704	678	728	732	2,842
2008	545	630	994	744	2,913
2007	632	726	972	772	3,102
2006	620	598	692	759	2,669
2005	543	622	762	757	2,684
2004	497	626	630	598	2,351
2003	571	538	646	624	2,379

#### LIQUIDITY AND CAPITAL RESOURCES

Our principal source of capital has been cash flow from our operations. We have achieved continuous positive operating cash flow over the last nine fiscal years. We believe that our existing capital and anticipated funds from operations will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for the foreseeable future. Thereafter, if cash generated from operations is insufficient to satisfy our capital requirements, we may open a revolving line of credit with a bank, or we may have to sell additional equity or debt securities or obtain expanded credit facilities. In the event such financing is needed in the future, there can be no assurance that such financing will be available to us, or, if available, that it will be in amounts and on terms acceptable to us. If cash flows from operations become insufficient to continue operations at the current level, and if no additional financing was obtained, then management would restructure the Company in a way to preserve its pharmaceutical business while maintaining expenses within operating cash flows.

We are not aware of any trends or demands, commitments, or uncertainties that are reasonably likely to result in a decrease in liquidity of our assets. The trend over the last nine years has been increasing cash deposits from our operating cash flows, and we expect that trend to continue for the foreseeable future. We have no material commitments for capital expenditures as of the end of the latest fiscal period.

We continue to seek opportunities for strategic acquisitions. If one or more such acquisition is identified, a substantial portion of our cash reserves may be required to complete it; however, we intend to maintain sufficient cash reserves after any acquisition to provide reasonable assurance that outside financing will not be necessary to continue operations. If we identify an attractive acquisition that would require more cash to complete than we are willing or able to use from our cash reserves, we will consider financing options to complete the acquisition, including obtaining loans and issuing additional securities.

#### UNUSUAL OR INFREQUENT EVENTS

There have been no unusual or infrequent events or other significant economic changes that have affected reported income, however, income may be impacted in the future by the sale of our Words+ subsidiary.

#### KNOWN TRENDS OR UNCERTAINTIES

We are not aware of any trends or uncertainties expected to impact net sales or revenues from the operations of our pharmaceutical business segment. The recent trend toward consolidation in the pharmaceutical industry has not had a negative effect on our sales to that industry, and we believe that the need for improved productivity in the research and development activities directed toward developing new medicines will continue to result in increasing adoption of simulation and modeling tools such as those we produce.

New product developments in the pharmaceutical business segments could result in increased revenues and earnings if they are accepted by our markets; however, there can be no assurances that new products will result in significant improvements to revenues or earnings. For competitive reasons, we do not disclose all of our new product development activities.

Our continued quest for acquisitions in the pharmaceutical business segment could result in a significant change to revenues and earnings if one or more such acquisitions are completed. It is our intent to only complete acquisitions that would add to both revenues and earnings; however, there can be no assurances that any acquisitions that may be completed will in fact result in both increased revenues and earnings.

We entered into a Stock Purchase Agreement with Prentke Romich Company (PRC) to sell all of the stock of Words+ to PRC for \$2.1 million, subject to adjustments for changes in net working capital. The full text of this agreement was filed as Exhibit 10.1 in Form 8-K on November 16, 2011 and is incorporated by reference. If this transaction is closed, then the Words+ business segment will be reported as discontinued operations.

#### **INFLATION**

We have not been affected materially by inflation during the periods presented, and no material effect is expected in the near future.

#### **OFF-BALANCE SHEET ARRANGEMENTS**

As of August 31, 2011, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties.

#### RECENTLY ISSUED ACCOUNTING STANDARDS

In September 2009, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2009-14 which amends Statement of Position ("SOP") 97-2, "Software Revenue Recognition", to exclude tangible products containing software components and non-software components that function together to deliver the product's essential functionality. ASU 2009-14 applies to revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with early application permitted with Emerging Issues Task Force ("EITF") 08-1. We adopted this standard in the first quarter of fiscal 2011. We believe adoption did not have a material effect on the Company's consolidated financial statements.

In September 2009, the FASB issued ASU 2009-13, "Revenue Arrangements with Multiple Deliverables" ("EITF 08-1"). ASU 2009-13 amends EITF 00-21, "Revenue Arrangements with Multiple Deliverables", to require an entity to use an estimated selling price when vendor-specific objective evidence or acceptable third-party evidence does not exist for any products or services included in a multiple element arrangement. The arrangement consideration should be allocated among the products and services based upon their relative selling prices, thus eliminating the use of the residual method of allocation. ASU 2009-13 also requires expanded qualitative and quantitative disclosures regarding significant judgments made and changes in applying the guidance. ASU 2009-13 applies to fiscal years beginning after June 15, 2010, with early application permitted. We adopted ASU 2009-13 in June 2011. We believe adoption did not have a material effect on the Company's consolidated financial statements.

#### CRITICAL ACCOUNTING POLICIES

Our consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. These estimates and assumptions are affected by management's application of accounting policies. Critical accounting policies for us include revenue recognition, accounting for capitalized software development costs, and accounting for income taxes.

#### Revenue Recognition

We recognize revenue related to software licenses and software maintenance in accordance with the FASB Accounting Standard Codification ("ASC") 985-605. Product revenue is recorded when the following conditions are met: 1) evidence of arrangement exists, such as signed purchase orders from customers or executed contracts, 2) delivery has been made, such as unlocking the software on the customer's computer(s), 3) the amount is fixed, and 4) it is collectible. Post-contract customer support ("PCS") obligations are insignificant; therefore, revenue for PCS is recognized at the same time, and the costs of providing such support services are accrued and amortized over the obligation period.

As a byproduct of ongoing improvements and upgrades to our software, some modifications are provided to customers who have already licensed software during their license term at no additional charge. We consider these modifications to be minimal, as they are not changing the basic functionality or utility of the software, but rather adding convenience, such as being able to plot some additional variable on a graph in addition to the numerous variables that had been available before. Such software modifications for any single product have been typically once or twice per year, sometimes more, sometimes less. Thus, they are infrequent. We provide, for a fee, additional training and service calls to our customers and recognize revenue at the time the training or service call is provided.

We enter into one-year license agreements with most of our customers for the use of our pharmaceutical software products. However, from time to time, we enter into multi-year license agreements. We unlock and invoice software one year at a time for multi-year licenses. Therefore, revenue is recognized one year at a time.

We recognize contract study revenue either equally over the term of the contract or using the percentage of completion method, depending upon how the contract studies are engaged, in accordance with FASB ASC 605-35. To recognize revenue using the percentage of completion method, we must determine whether we meet the following criteria: 1) there is a long-term, legally enforceable contract, 2) it is possible to reasonably estimate the total project costs, and 3) it is possible to reasonably estimate the extent of progress toward completion.

#### Capitalized Computer Software Development Costs

Software development costs are capitalized in accordance with FASB ASC 985-20. Capitalization of software development costs begins upon the establishment of technological feasibility and is discontinued when the product is available for sale.

The establishment of technological feasibility and the ongoing assessment for recoverability of capitalized software development costs require considerable judgment by management with respect to certain external factors including, but not limited to, technological feasibility, anticipated future gross revenues, estimated economic life, and changes in software and hardware technologies. Capitalized software development costs are comprised primarily of salaries and direct payroll-related costs and the purchase of existing software to be used in our software products.

Amortization of capitalized software development costs is provided on a product-by-product basis on the straight-line method over the estimated economic life of the products (not to exceed five years). Amortization of software development costs amounted to \$688,651 and \$644,015 for the fiscal years ended August 31, 2011 and 2010, respectively. We expect future amortization expense to vary due to increases in capitalized computer software development costs.

We test capitalized computer software costs for recoverability whenever events or changes in circumstances indicate that the carrying amount may not be recoverable within a reasonable time.

#### **Income Taxes**

We utilize FASB ASC 740-10 which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns.

Under this method, deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The provision for income taxes represents the tax payable for the period and the change during the period in deferred tax assets and liabilities.

#### **Stock-Based Compensation**

The Company accounts for stock options using the modified prospective method in accordance with FASB ASC 718-10. Under this method, compensation costs include: (1) compensation cost for all share-based payments granted prior to, but not yet vested as of September 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123 amortized over the options' vesting period, and (2) compensation cost for all share-based payments granted subsequent to September 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of FASB ASC 718-10, amortized on a straight-line basis over the options' vesting

period. Stock-based compensation was \$155,252 and \$127,597 for the years ended August 31, 2011 and 2010, respectively, and is included in the consolidated statements of operations as Consulting, Salaries, and Research and Development expense.

#### Principles of Consolidation

The consolidated financial statements include the accounts of Simulations Plus, Inc. and its wholly owned subsidiary, Words+, Inc. All significant intercompany accounts and transactions are eliminated in consolidation.

#### **Estimates**

Our consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. These estimates and assumptions are affected by management's application of accounting policies. Actual results could differ from those estimates. Significant accounting policies for us include revenue recognition, accounting for capitalized software development costs, and accounting for income taxes.

#### ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable because the Company is a smaller reporting company.

#### ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The responses to this item are included elsewhere in this Form 10-K (see pages F1 – F23) and incorporated herein by reference.

# ITEM 9 – CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There have been no changes to our public accountants during the past two years.

#### ITEM 9A - CONTROLS AND PROCEDURES

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of August 31, 2011, the end of the fiscal year covered by this report.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting, as defined in Exchange Act Rule 13a-15(f). Our internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal controls over financial reporting based on the framework established by the Committee of Sponsoring Organizations for the Treadway Commission. Based on our evaluation under the framework, including the completion and review of internal review assessment forms and the completion and review of financial reporting information systems and controls checklists in the framework, our management concluded that our internal control over financial reporting was effective as of August 31, 2011.

No changes were made in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Our management, including our CEO and CFO, does not expect that our disclosure controls or internal controls over financial reporting will prevent all errors or all instances of fraud. A control system, no matter how well-designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and any design may not succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitation of a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

#### ITEM 9B - OTHER INFORMATION

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#### **PART III**

#### ITEM 10 – DIRECTORS, AND EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

#### Code of Ethics

Our code of ethics is posted on our website: www.simulations-plus.com.

#### Changes to Procedures for Recommending Nominees to the Board of Directors

There have been no material changes to the procedures by which security holders may recommend nominees to our board of directors since we last described such procedures.

The remaining information required by Item 10 is incorporated by reference from the section entitled "Board matters and corporate governance" in the Company's definitive proxy statement (the "Proxy Statement") to be distributed in connection with its 2012 Annual Shareholders' Meeting.

#### ITEM 11 - EXECUTIVE COMPENSATION

The information required by Item 11 is incorporated by reference from the sections entitled "Executive compensation and other information" in the Company's Proxy Statement to be distributed in connection with its 2012 Annual Shareholders' Meeting.

# ITEM 12 - SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 12 is incorporated by reference from the section entitled "Security ownership of certain beneficial owners and management" in the Company's Proxy Statement to be distributed in connection with its 2012 Annual Shareholders' Meeting.

#### ITEM 13 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by Item 13 is incorporated by reference from the sections entitled "Transactions with related persons" and "Independence of the Board of Directors" the Company's Proxy Statement to be distributed in connection with its 2012 Annual Shareholders' Meeting.

#### ITEM 14 - PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by Item 14 is incorporated by reference from the section of the proposal entitled "Ratification of selection of independent registered public accounting firm" in the Company's Proxy Statement to be distributed in connection with its 2012 Annual Shareholders' Meeting.

#### **PART IV**

#### ITEM 15 - EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) (1) Financial Statements. The consolidated financial statements are included in this Annual Report.

- (2) Financial Statement Schedules. All financial statement schedules have been omitted since the information is either not applicable or required or was included in the financial statements or notes included in this Annual Report on Form 10-K.
- (3) List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.
- (b) Exhibits. The following exhibits are filed as part of this report. Those exhibits marked with a (†) refer to management contracts or compensatory plans or arrangements.

<b>EXHIBIT</b>	
NUMBER	DESCRIPTION
3.1	Articles of Incorporation of Simulations Plus, Inc. (7)
3.2	Amended and Restated Bylaws of Simulations Plus, Inc. (7)
4.1	Articles of Incorporation of Simulations Plus, Inc. (incorporated by reference to Exhibit 3.1 hereof) and
	Bylaws of Simulations Plus, Inc. (incorporated by reference to Exhibit 3.2 hereof)
4.2	Form of Common Stock Certificate (1)
4.3	Share Exchange Agreement (1)
10.1	Simulations Plus, Inc. 1996 Stock Option Plan (the "Option Plan") and forms of agreements relating
	thereto $(1)$ $(\dagger)$
10.24	Exclusive Software License Agreement by and between Simulations Plus, Inc. and Therapeutic
	Systems Research Laboratories dated June 30, 1997. (2)
10.34	OEM/Remarketing Agreement between Words+, Inc. and Eloquent Technology, Inc. (6)
10.41	Technology Transfer Agreement between Sam Communications, LLC. (6)
10.43	Lease Agreement by and between Simulations Plus, Inc. and Venture Freeway, LLC. (3)
10.46	Simulations Plus, Inc. 2007 Stock Option Plan (the "2007 Option Plan") (5) (†)
10.47	Lease extension agreement by and between Simulations Plus, Inc. and Crest Development (7)
10.48	Employment Agreement by and between the Company and Walter S. Woltosz (8) (†)
10.49	Bill of Sale by and between Simulations Plus, Inc. and Entelos, Inc. dated September 19, 2011 (9)
10.	Stock Purchase Agreement by and among Simulations Plus, Inc., Words+, Inc., and Prentke Romich
50	Company dated November 15, 2011 (10)
21.1	List of Subsidiaries (8)
23.1	Consent of Rose, Snyder and Jacobs (8)
31.1	Rule 13a-14(a)/15d-14(a) – Certification of Chief Executive Officer (CEO). (8)
31.2	Rule 13a-14(a)/15d-14(a) – Certification of Chief Financial Officer (CFO). (8)
32	Section 1350 – Certification of CEO and CFO. (8)

<sup>(1)</sup> Incorporated by reference to the Company's Registration Statement on Form SB-2 (Registration No. 333-6680) filed on March 25, 1997.

- (2) Incorporated by reference to the Company's Form 10-KSB filed December 15, 1997 (Commission file No. 333-05400-LA).
- (3) Incorporated by reference to the Company's Form 10-KSB filed December 15, 1997 (Commission file No. 333-05400-LA).
- (4) Incorporated by reference to the Company's Form 10-K filed November 30, 2010 (Commission file No. 001-32046).
- (5) Incorporated by reference to the Company's Form 10-Q filed January 13, 2010 (Commission No. 001-32046)
- (6) Incorporated by reference to the Company's Form 10-K/A filed on March 1, 2010 (Commission file No. 001-32046).
- (7) Incorporated by reference to the Company's Form 10-K filed November 29, 2010 (Commission No. 001-32046)
- (8) Filed herewith.
- (9) Incorporated by reference to the Company's Form 8-K filed September 22, 2011 (Commission No. 001-32046)
- (10) Incorporated by reference to the Company's Form 8-K filed November 16, 2011 (Commission No. 001-32046)
- (c) Financial Statement Schedule.

See Item 15(a)(2) above.

#### **SIGNATURES**

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Lancaster, State of California, on November 28, 2011.

#### SIMULATIONS PLUS, INC.

/s/ Momoko A. Beran By:

> Momoko A. Beran Chief Financial Officer

In accordance with Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on.

Title Signature

Chairman of the Board of Directors and Chief Executive Officer /s/ Walter S. Woltosz

Walter S. Woltosz (Principal executive officer)

Secretary and Director of the Company /s/ Virginia E. Woltosz

Virginia E. Woltosz

Director /s/ Dr. David Z. D'Argenio

Dr. David Z. D'Argenio

/s/ Dr. Richard R. Weiss Director

Dr. Richard R. Weiss

/s/ Harold W. Rosenberger Director

Harold W. Rosenberger

/s/ Momoko A. Beran Chief Financial Officer of the Company

Momoko A. Beran (Principal financial officer and principal accounting officer)

# SIMULATIONS PLUS, INC. AND SUBSIDIARY CONTENTS August 31, 2011 and 2010

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Simulations Plus, Inc. Lancaster, California

We have audited the accompanying consolidated balance sheets of Simulations Plus, Inc. (a California corporation) and Subsidiary as of August 31, 2011 and 2010 and the related consolidated statements of operations, shareholders' equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards established by the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Simulation Plus, Inc. and Subsidiary as of August 31, 2011 and 2010, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Rose, Snyder & Jacobs A Corporation of Certified Public Accountants

Encino, California

November 28, 2011

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# SIMULATIONS PLUS, INC. AND SUBSIDIARY CONSOLIDATED BALANCE SHEETS

ASSETS		0.4
	C	ust 31,
	2011	2010
Current assets	<b>#10.101.010</b>	Φο (21 7(2
Cash and cash equivalents	\$10,181,049	\$9,631,762
Income tax refund receivable	259,434	225,510
Accounts receivable, net of allowance for doubtful accounts and estimated	1 == 1 000	1 201 250
contractual discounts of \$233,385 and \$421,118	1,774,038	1,291,350
Contracts receivable	185,816	184,081
Inventory	391,653	554,867
Prepaid expenses and other current assets	180,761	138,163
Deferred income taxes (note 6)	302,076	364,264
Total current assets	13,274,827	12,389,997
Capitalized computer software development costs,		
net of accumulated amortization of \$5,176,408 and \$4,487,757	2,408,658	2,186,419
Property and equipment, net (note 3)	163,538	55,984
Customer relationships, net of accumulated amortization of \$126,172 and \$118,442	1,870	9,600
Other assets	18,445	18,445
Total assets	\$15,867,338	\$14,660,445
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$292,482	\$239,424
Accrued payroll and other expenses	494,821	511,107
Accrued bonuses to officer	-	60,000
Accrued income taxes	168,897	261,861
Accrued warranty and service costs	43,727	35,586
Deferred revenue	141,191	96,092
Total current liabilities	1,141,118	1,204,070
Long-term liabilities		
Deferred income taxes (note 6)	689,605	410,523
	,	,
Total liabilities	1,830,723	1,614,593
	, ,	, ,
Commitments and contingencies (note 4)		
( )		
Shareholders' equity (note 5)		
Preferred stock, \$0.001 par value 10,000,000 shares authorized no shares issued and		
outstanding	_	_
Common stock, \$0.001 par value 50,000,000 shares authorized 15,572,943 and		
15,833,006 shares issued and outstanding	4,044	4,304
Additional paid-in capital	4,167,650	5,891,268
Authona palu-in capitai	7,107,030	3,071,200

Retained earnings	9,864,921	7,150,280		
Total shareholders' equity	14,036,615	13,045,852		
Total liabilities and shareholders' equity	\$15,867,338	\$14,660,445		
The accompanying notes are an integral part of these consolidated financial statements.				
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# SIMULATIONS PLUS, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF OPERATIONS

For the years ended

	Ano	ust 31,
	2011	2010
Net sales	\$11,719,758	\$10,711,829
Cost of sales	2,878,891	2,545,709
Gross profit	8,840,867	8,166,120
Operating expenses Selling, general, and administrative	4,305,156	4,325,621
Research and development	935,196	969,871
Total operating expenses	5,240,352	5,295,492
Income from operations	3,600,515	2,870,628
Other income (expense)	01.061	101.545
Interest income Missellements income	91,861	101,545
Miscellaneous income	1,000 76,416	1,231 130,150
Gain on currency exchange Gain on sale of assets	240	1,993
Interest expense	(118	) (1,045 )
Total other income (expense)	169,399	233,874
Income before income taxes	3,769,914	3,104,502
Provision for income taxes (note 6)		
Deferred income taxes	, ,	) (289,829 )
Current Income taxes	(771,177	) (658,600 )
Net income	\$2,714,641	\$2,156,073
Basic earnings per share	\$0.17	\$0.14
Diluted earnings per share	\$0.17	\$0.13
Weighted-average common shares outstanding		
Basic	15,540,047	15,831,294
Diluted	16,082,454	16,513,018

The accompanying notes are an integral part of these consolidated financial statements.

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# SIMULATIONS PLUS, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY For the years ended August 31,

	Comm	non Stock	Additional Paid-In	Retained	
	Shares	Amount	Capital	Earnings	Total
Balance, August 31, 2009	15,700,382	4,172	5,572,411	4,994,207	10,570,790
Exercise of stock options	632,674	632	94,290		94,922
Stock-based Compensation			127,597		127,597
Stock Repurchases	(500,050	) (500	) (1,033,607	)	(1,034,107)
Deferred tax adjustments			1,130,577		1,130,577
Net income				2,156,073	2,156,073
Balance, August 31, 2010	15,833,006	\$4,304	\$5,891,268	\$7,150,280	\$13,045,852
Exercise of stock options	415,776	416	144,545		144,961
Stock-based Compensation			155,252		155,252
Stock Repurchases	(675,839	) (676	) (2,047,496	)	(2,048,172)
Deferred tax adjustments			24,081		24,081
Net income				2,714,641	2,714,641
Balance, August 31, 2011	15,572,943	\$4,044	\$4,167,650	\$9,864,921	\$14,036,615

The accompanying notes are an integral part of these consolidated financial statements.

# SIMULATIONS PLUS, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended

	August 31,	
	2011	2010
Cash flows from operating activities		
Net income	\$2,714,641	\$2,156,073
Adjustments to reconcile net income to net cash provided by operating activities		
Depreciation and amortization of property and equipment	50,922	25,215
Amortization of customer relationships	7,730	13,714
Amortization of capitalized computer software development costs	688,651	644,014
Bad debts	-	176,978
Excess tax benefits from share-based arrangements	(24,081	) (1,130,577 )
Stock-based compensation	155,252	127,597
Gain on sale of equipment	(240	) (1,993 )
Deferred income taxes	341,270	289,829
(Increase) decrease in		
Accounts receivable and Contracts receivable	(484,423	) 335,216
Income tax refundable	(33,924	) 298,641
Inventory	163,214	(228,940)
Prepaid expenses and other assets	(42,598	) 24,532